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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/003,915	11/02/2001	Anthony J. Mauro	460.2115USU	7768

7590 09/25/2009
Charles N.J. Ruggiero, Esq.
Ohlandt, Greeley, Ruggiero & Perle, L.L.P.
10th Floor
One Landmark Square
Stamford, CT 06901-2682

EXAMINER

ANDERSON, CATHARINE L

ART UNIT	PAPER NUMBER
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3761

MAIL DATE	DELIVERY MODE
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09/25/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/003,915	Applicant(s) MAURO ET AL.	
	Examiner Lynne Anderson	Art Unit 3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 July 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,7,19,20,27 and 38-40 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,7,19,20,27 and 38-40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

1. Applicant's arguments filed 7 July 2007 have been fully considered but they are not persuasive.
2. In response to the applicant's argument that the claimed ranges of amounts of the antibacterial agent and the finishing agent are shown in Table 1 of the present specification to be critical, it is noted that the claimed range for the antibacterial agent remains broader than the amounts shown in Table 1 to provide a reduction in bacterial growth, and therefore have not been shown to be critical or provide unexpected results.
3. With respect to claims 39 and 40, it is noted that the claims disclose the composition "consists essentially of" the claimed antibacterial agent and surfactant. The prior art composition (i.e. the composition of Baker) may therefore include additional components, so long as the additional components do not materially affect the basic and novel characteristics of the claimed invention (see MPEP 2111.03). The composition disclosed by Baker comprises an oil-in-water emulsion, a surfactant, and a halogen-containing antibacterial compound, as disclosed in column 5, lines 13-19. Therefore, absent a showing that an oil-in-water emulsion would materially affect the claimed invention, the limitation "consisting essentially of" will be construed to include the emulsion of Baker.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1, 7, 19, 20, 27, and 38-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Baker, Jr. et al. (6,559,189) in view of Fischetti et al. (6,335,012).

6. Baker discloses all aspects of the claimed invention with the exception of the amount of antibacterial agent and finishing agent by weight of the tampon, and the finishing agent being a polyoxyethylene fatty acid ester. Baker discloses a tampon, as described in column 13, lines 53-54, comprising a composition disposed in the tampon, as described in column 7, lines 50-52 and 54-55. The composition comprises an anti-bacterial agent and a finishing agent. The anti-bacterial agent is a quaternary ammonium compound, as described in column 5, line 64, to column 7, lines 12, specifically alkyl dimethyl benzyl ammonium chloride and alkyl dimethyl ethylbenzyl ammonium chloride. The finishing agent is a nonionic surfactant, polyethylene glycol, as described in column 5, lines 54-56 and 62. The composition further comprises a preservative, as described in column 5, lines 22-27. Baker discloses the composition of the claimed invention, and the antibacterial properties are inherent in the chemicals comprising the composition. Baker therefore inherently discloses a composition effective to neutralize the production of TSST-1 toxin and reduce *Staphylococcus aureus* bacteria growth, and fulfills all limitations of the claims.

7. Baker discloses the amount of anti-bacterial agent as based on the total weight of the composition, as described in column 30, lines 38-41, but remains silent as to the amount of anti-bacterial agent as based on the total weight of the tampon. It would

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have been obvious to one of ordinary skill in the art at the time of invention to make the tampon of Baker comprising 0.1% to 2.5% by weight of the anti-bacterial agent, since it has been held that where the general conditions of the claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art.

8. Fischetti discloses polyoxyethylene fatty acid ester and polyoxyethylene sorbital ester as being art-recognized equivalent surfactants, as described in column 11, lines 14-16, which are suitable for use in tampons, as described in column 12, lines 20-21 and 26.

9. It would therefore be obvious to one of ordinary skill in the art at the time of invention to have the surfactant of Baker comprise a polyoxyethylene fatty acid ester, as taught by Fischetti, since the examiner takes official notice of the equivalence of polyoxyethylene fatty acid ester and polyoxyethylene sorbital ester for their use as surfactants in tampons, and the selection of any of these equivalents would be within the level of ordinary skill in the art.

10. Baker discloses the amount of finishing agent as based on the total weight of the composition, as described in column 30, lines 33-33, but remains silent as to the amount of finishing agent as based on the total weight of the tampon. It would have been obvious to one of ordinary skill in the art at the time of invention to make the tampon of Baker comprising about 2.5% by weight of the finishing agent, since it has been held that where the general conditions of the claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art.

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11. With respect to claims 39 and 40, the composition disclosed by Baker comprises an oil-in-water emulsion, a surfactant, and a halogen-containing antibacterial compound, as disclosed in column 5, lines 13-19. Since the emulsion does not materially affect the basic and novel characteristics of the claimed invention, the composition of Baker, as modified by Fischetti, fulfills the claimed limitations.

Conclusion

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lynne Anderson whose telephone number is (571)272-4932. The examiner can normally be reached on Monday through Friday.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tanya Zalukaeva can be reached on (571) 272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/L. A./

Examiner, Art Unit 3761

/Tatyana Zalukaeva/

Supervisory Patent Examiner, Art Unit 3761